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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,991	06/21/2007	Eric James Wall	CHM-021M	8880

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EXAMINER	
PRICE, NATHAN R	

ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
10/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/597,991	**Applicant(s)** WALL ET AL.	
	Examiner NATHAN R. PRICE	**Art Unit** 3763	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 05 October 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Continuation of 11. does NOT place the application in condition for allowance because:

1. Applicant's arguments filed October 5, 2009 have been fully considered but they are not persuasive.

2. Applicant argues on page 7 of the Remarks that "a person of ordinary skill in the art would not understand that extreme exceptions (individuals with high pain thresholds and injection areas experiencing low pain) qualify the entire range of needle sizes disclosed in Miskinyar as being capable of administering a painless needle insertion". However, Examiner notes that Applicant is still, with the characterization of Examiner's interpretation as referencing "extreme" exceptions, interpreting the claim limitation too narrowly. Nowhere in the claim is the function of the device limited to use on a human. One of ordinary skill in the art at the time the invention was made would understand that pain threshold would not only vary from person to person and from injection location to injection location, but also between species. Applicant cites the portion of the specification which ties painless injection to the needle diameter. However, Examiner relies upon Woehr and not Minskinyar for teaching needle diameter.

3. Regarding Applicant's arguments on pages 7 through 8 of the Remarks in reference to the teachings of Woehr, Examiner maintains that Woehr does suggest to one of ordinary skill in the art at the time the invention was made that needle sizes in the range claimed would be useful. The fact that he discloses other needle sizes as well outside of the range claimed does not detract from the teaching of the needle sizes within the claimed range. Woehr shows that one having ordinary skill in the art at the time the invention was made would understand that these needle diameters would be available and ideally suited for the purposes taught by Woehr in par. 0079.

4. Regarding Applicant's arguments on pages 8 through 9 of the Remarks that the "retraction spring 102" of Miskinyar is "misnomered" and "cannot retract the needle from its second extended position to a third position". Applicant has misunderstood the operation of the Miskinyar apparatus, and is misinterpreting the "force required to advance the piston". Spring 102 is clearly delineated by Miskinyar as a "retraction spring 102" (col. 5, ln. 28). Furthermore, it would be necessary for the force of the retraction spring to be less than the force required to *advance* the piston so that the device would be capable of actuating. The force required to advance the piston is the force required to move piston 100 through medication chamber 98 (see fig. 8). Initial actuation of the device of fig. 8 results in spring 128 moving the entire needle/medicament reservoir assembly distally so that needle 94 penetrates the tissue. After penetration, continued force from 128 moves piston 100 distally to eject medication from chamber 98. Once such actuation is complete, the force exerted by *retraction* spring 102 is greater than distally directed force of spring 128, and retraction of the entire needle/piston apparatus is effected.

5. Examiner addressed the remainder of Applicant's arguments fully in the previous Office Action..